

Europäisches **Patentamt** 

European **Patent Office**  Office européen des brevets

REC'D 2 1 DEC 2004 WIPO

Bescheinigung

Certificate

**Attestation** 

Die angehefteten Unterlagen stimmen mit der ursprünglich eingereichten Fassung der auf dem nächsten Blatt bezeichneten europäischen Patentanmeldung überein.

The attached documents are exact copies of the European patent application conformes à la version described on the following page, as originally filed.

Les documents fixés à cette attestation sont initialement déposée de la demande de brevet européen spécifiée à la page suivante.

Patent application No. Demande de brevet nº Patentanmeldung Nr.

03026854.4

SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

> Der Präsident des Europäischen Patentamts; Im Auftrag

For the President of the European Patent Office

Le Président de l'Office européen des brevets p.o.

R C van Dijk



Anmeldung Nr:

Application no.: 03026854.4

Demande no:

Anmeldetag:

Date of filing: 24.11.03

Date de dépôt:

Anmelder/Applicant(s)/Demandeur(s):

Gambro Lundia AB Magistratsvägen 16 22 643 Lund SUEDE

Bezeichnung der Erfindung/Title of the invention/Titre de l'invention: (Falls die Bezeichnung der Erfindung nicht angegeben ist, siehe Beschreibung. If no title is shown please refer to the description. Si aucun titre n'est indiqué se referer à la description.)

End-cap assembly for a filter

In Anspruch genommene Prioriät(en) / Priority(ies) claimed /Priorité(s) revendiquée(s)
Staat/Tag/Aktenzeichen/State/Date/File no./Pays/Date/Numéro de dépôt:

Internationale Patentklassifikation/International Patent Classification/Classification internationale des brevets:

A61M1/14

Am Anmeldetag benannte Vertragstaaten/Contracting states designated at date of filing/Etats contractants désignées lors du dépôt:

AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LU MC NL PT RO SE SI SK TR LI

24. Nov. 2003

The present invention relates to an end-cap assembly for a filter, in particular, to an end-cap assembly for a filter used in an extracorporeal treatment of blood. The invention also relates to a degassing device included or connected to an end-cap assembly.

5

10

A conventional filter for extracorporeal treatment of blood comprises a first and a second compartments separated by a membrane, the first compartment having an inlet and an outlet for the circulation of blood therethrough and the second compartment having an outlet for draining a liquid (e.g. plasma water, plasma, used dialysis liquid) and an inlet when the treatment (e.g. hemodialysis) requires the circulation of a treatment liquid (e.g. a dialysis liquid) in the second compartment. The membrane is enclosed in an elongated tubular housing closed at both ends by an end-cap comprising a nozzle used as an inlet/outlet port for the first compartment.

15

20

Such filters are used in various extracorporeal treatments of blood, such as hemodialysis, hemofiltration, hemodiafiltration, plasmapheresis. The same type of filter, usually referred to as hemodialyzer or hemofilter, is used for hemodialysis, hemofiltration, hemodiafiltration. The main difference between a hemodialyzer and a plasmafilter (i.e. a filter used in plasmapheresis) is the pore size of their respective membrane, a membrane for plasmapheresis allowing the proteins contained in blood to migrate therethough, whereas a membrane for hemodialysis does not.

25

30

In all these treatments, blood is withdrawn from the patient, flown through the first compartment of the filter, and returned to the patient. In hemodialysis, a dialysis liquid is simultaneously flown though the second compartment of the filter and the metabolic wastes (urea, creatinine) contained in blood migrate by diffusion through the membrane into the second compartment. In hemofiltration, a pressure difference is created across the membrane so that plasma water flows through the membrane into the second compartment of the filter. Here, metabolic wastes migrate by convection into the second compartment. In order to compensate for the loss of bodily fluid, the patient is simultaneously infused a sterile substitution solution. Hemodiafiltration is a combination of hemodialysis and hemofiltration,

5

10

15

20

25

30

and, in this treatment, a dialysis liquid is flown through the second compartment and a substitution liquid is infused into the patient. In plasmapheresis, a pressure difference is created across the membrane so that plasma (i.e. plasma water and proteins) flows through the membrane into the second compartment of the filter. Once treated, the plasma is returned to the patient.

A machine for performing any of the above treatments comprises a peristaltic pump for withdrawing blood from a patient through a so-called arterial line connected at one end to the vascular circuit of the patient and at the other end to the inlet of the first compartment of a filter, for pumping blood into the filter, and for returning blood to the patient through a so-called venous line connected at one end to the outlet of the first compartment of the filter and at the other end to the vascular circuit of the patient. The treatment machine also usually comprises a first blood pressure sensor for measuring the pressure of blood in the arterial line upstream of the pump, a second blood pressure sensor for measuring the pressure of blood in the arterial line downstream of the pump, a third pressure sensor for measuring the pressure of blood in the venous line, a bubble detector for detecting air bubbles in the venous line and a clamp for closing the venous line, for example when air bubbles are detected by the bubble detector. An arterial line typically comprises the following components connected together by segments of flexible tubes: a first Luer connector for connection to an arterial cannula, an arterial bubble trap, a pump hose for cooperating with the rotor of the peristaltic pump of the treatment machine, and a second Luer connector for connection to the inlet of the first compartment of the filter. A venous line typically comprises the following components connected together by segments of flexible tubes: a first Luer connector for connection to the outlet of the first compartment of the filter, a venous bubble trap, and a second Luer connector for connection to a venous cannula. Usually, the first and third pressure sensors of the machine are connected to the arterial and venous bubble trap respectively, when the treatment machine, the arterial line, the venous line and the filter are assembled in view of a treatment.

A conventional bubble trap is basically an elongated container that, in use, is held vertically. The container has an inlet and an outlet for blood that are arranged so

as not to be adjacent. It comprises also, in an upper location, a pressure measuring port for connection to a pressure sensor, an infusion port for infusing a liquid (e.g. a drug or a sterile saline solution) and an injection port for adding or removing air into or from the bubble trap so as to adjust the level of blood therein. In use, the bubble trap contains a volume of blood in a lower part that transiently stagnates therein so as to let gas bubbles and micro bubbles escape by gravity and join an upper part of the container full of air. In a conventional bubble trap, there is therefore always an interface blood-air.

Besides the fact that, in order to properly operate, conventional bubble traps must contain a certain volume of blood (which conflicts with the long lasting effort of minimizing the extracorporeal volume of blood in blood treatments), their use is limited to relatively short treatment sessions because of the blood clotting resulting from the permanent blood-air interface. In this respect, they are adapted to chronic treatment (a treatment session for a chronic patient usually lasts about four hours), but they cannot be used for intensive care treatment (the treatment of an acute patient can last several days),

In addition, the assemblage of a bubble trap and the line connected thereto to a treatment machine and the setting of the blood level therein is relatively time consuming.

An object of the invention is to design and end-cap assembly that remedies the above mentioned limits of conventional extracorporeal blood circuit.

25

5

According to the invention, an end-cap assembly for a filtration device comprises:

- an end-cap having a peripheral wall for connection to an end of the housing of a filtration device; and
- a degassing device connected to the end-cap, comprising:
- a first chamber for receiving a liquid flowing out of a first compartment of the filter into the end-cap,
  - a second chamber in communication with the first chamber and having an opening closed by a hydrophobic membrane, and
  - an outlet port connected to the second chamber for discharging the liquid.

Additional features are as follows:

10

15

20

25

- The second chamber is in communication with the first chamber through a passageway that has a lesser cross-section than a cross-section of the second chamber so that a flow of liquid from the first chamber into the second chamber decreases within the second chamber.
- The first chamber, the second chamber and the passageway therebetween are arranged with respect to each other so that a flow pattern of a liquid flowing from the first chamber, through the second chamber and to the outlet port comprises a component that is tangential to the membrane.
- The first chamber, the second chamber and the passageway therebetween are arranged with respect to each other so that a flow of liquid flowing from the first chamber, through the second chamber and to the outlet port keeps gas bubbles in motion along an inner surface of the hydrophobic membrane.

This end-cap assembly presents several advantages.

First, it is very efficient and remains efficient over time. Also its allows for a compact design, i.e. a small internal volume. For example, it is possible to design such an end-cap assembly with a total internal volume that is about half of the blood volume in conventional bubble traps.

Second, the degassing device operates without air-blood interface and it is therefore particularly adapted to long lasting treatments (e.g. continuous renal replacement therapies).

Third, it does not require any specific activity for its mounting on a treatment machine or for its setting in use (no adjustment of the level of the air-blood interface since there is no air-blood interface).

- 30 Other additional or alternative features of the invention are as follows:
  - The first chamber comprises a downstream portion having a cross-section that is substantially the same as the cross-section of the passageway between the first and the second chamber.

- The first chamber comprises an upstream portion having a decreasing crosssection, with a larger cross-section that is substantially the same as the crosssection of the housing and a smaller cross-section that is substantially the same as the cross-section of the passageway between the first chamber and the second chamber.

5

10

15

20

- The second chamber has a downstream portion that surrounds the passageway and forms an overflow for a fluid flowing from the first chamber into the second chamber.
- The cross-section of the passageway is substantially circular and the cross section of the second chamber that is level with the passageway is substantially annular and the ratio of the diameter of the passageway to the diameter of the second chamber at the level of the passageway is comprised between about 0.2 and about 0.5. A ratio of about 0.35 is particularly appropriate.
- The upstream portion of the second chamber has a decreasing cross-section, with a larger cross-section that is substantially level with the passageway and a smaller cross-section that is substantially level with the hydrophobic membrane. In particular, the upstream portion of the second chamber can be substantially frustoconical.
- The second chamber has a downstream portion that extends at least in part around the downstream portion of the first chamber.
  - The outlet port opens into the downstream portion of the second chamber at a location remote from the passageway.
- 30 Another object of the invention is a filter comprising such an end-cap assembly.

Still another object of the invention is a blood degassing device comprising:

- a first chamber having an inlet for receiving a flow of blood to be degassed;

- a second chamber in communication with the first chamber and having an opening closed by a hydrophobic membrane; and

- an outlet port connected to the second chamber for discharging blood, wherein the second chamber is in communication with the first chamber through a passageway that has a lesser cross-section than a cross-section of the second chamber so that a flow of blood from the first chamber into the second chamber decreases within the second chamber.

Other features and advantages of the invention will appear on reading the detailed description that follows. Reference will be made to the appended drawings in which:

Figure 1 is cross-section of a filter according to the invention along a plane that contains the longitudinal axis of the filter;

Figure 2 is a perspective view of a first embodiment of the end-cap assembly according to the invention;

Figure 3 is a cross-section view of the end-cap assembly of Figure 2 along a plane that contains the central axis of the end-cap;

15

30

Figure 4 is a perspective view, partially cut-away, of a second embodiment of the end-cap assembly according to the invention;

25 Figure 5 is cross-section view of the end-cap assembly of Figure 4 along a plane that contains the central axis of the end-cap;

Figure 6 is cross-section view of a third embodiment of the end-cap assembly according to the invention along a plane that contains the central axis of the end-cap; and

Figure 7 is cross-section view of a fourth embodiment of the end-cap assembly according to the invention along a plane that contains the central axis of the end-cap.

Figure 1 shows a hollow fiber filter 1 comprising a tubular housing 2 having a longitudinal axis 3, a semi-permeable membrane in the form a bundle of hollow fibers 4 extending within the housing 2 and secured thereto at both ends, and two end-caps 5, 6 closing the housing 2 at both ends. The ends of the fibers 4 are secured to the housing 2 by a potting compound in which they are embedded. The potting compound forms a disk 7 that extends perpendicularly to the longitudinal axis 3 of the housing 2. The ends of the fibers 4 open on an outer surface 8 of the disks 7 of potting material.

10

15

By construction, the hollow fiber filter 1 comprises a first and a second compartments separated from each other. The first compartment includes the interior of the hollow fibers 4 and the space delimited at each end of the filter between the outer surface 8 of the disk 7 of potting compound and the inner surface of the end-cap 5, 6, and the second compartment includes the space outside of the hollow fibers 4 that is delimited by the inner surface of the housing 2 and the inner surface 9 of the disks 7 of potting material. The housing 2 is fitted with two nozzles 10, 11 that give access to the second compartment.

20

25

The lower end-cap 6 comprises a circular end-wall 12 connected to a tubular peripheral wall 13 by which the end-cap 6 is secured to the housing 2. When the end-cap 6 is secured to the housing 2, as shown, the end-wall 12 is substantially perpendicular to the longitudinal axis 3 of the filter 1 and the tubular peripheral wall 13 is concentric to the housing 2. The end-cap 6 also comprises a tubular nozzle 14 connected to the end-wall 12 so that the central axis of the nozzle 14 coincides with the longitudinal axis 3 of the housing 2. The nozzle 14 forms the inlet to the first compartment.

30

The upper end-cap 5 comprises an annular end-wall 15 connected to a tubular peripheral wall 16 by which the end-cap 5 is secured to the housing 2. When the end-cap 5 is secured to the housing 2, as shown, the end-wall 15 is substantially perpendicular to the longitudinal axis 3 of the filter 1 and the tubular peripheral wall 16 is concentric to the housing 2.

According to the invention, the end-cap 5 is connected to a degassing device 20 so as to form the end-cap assembly that is shown in details in Figures 2 and 3. The degassing device 20 comprises a first chamber 21 for receiving a liquid flowing out of the first compartment of the filter 1 into the end-cap 5; a second chamber 22 in communication with the first chamber 21 and having an opening 23 closed by a hydrophobic membrane 24; and an outlet port 25 connected to the second chamber 22 for discharging the liquid.

The first chamber 21 is delimited by a funnel like wall 26 that is connected by its base to the end-wall 15 of the end-cap 5. The funnel like wall 26 has a central axis 27 that coincides with the longitudinal axis 3 of the housing 2. In the direction of the flow, the first chamber 21 has therefore an upstream portion having a decreasing cross-section and a downstream portion having a constant cross-section (unless otherwise specified, "cross-section" means here and hereunder the transversal cross-section with respect to the central axis 27; also, the "direction of flow" means the direction of flow from the first compartment of the filter 2 to the outlet port 25 through the first and the second chambers 21, 22 of the degassing device 20).

The second chamber 22 has an upstream portion and a downstream portion that extend on each side of a plane containing the mouth of the funnel like wall 26, which forms the passageway 28 between the first and the second chambers 21, 22. The downstream portion is delimited by a cylindrical wall 29 that is concentric to the tubular portion of the funnel like wall 26, and by a bottom wall 30 that is beveled with respect the central axis 27. The main reason for designing a bottom wall 30 that is beveled with respect the central axis 27 rather than a bottom wall that would be perpendicular to the central axis 27 and would be connected to a cylindrical wall having the same length as the tubular portion of the funnel like wall 26, is to limit the inner volume of the degassing device 20. It results from the respective arrangement of the first chamber 21 and of the downstream portion of the second chamber 22 that the second chamber forms an overflow for a liquid flowing from the first chamber 21 into the second chamber 22. Note that the outlet port 25 is connected to the second chamber 22 as far as possible from the passageway 28 between the two chambers.

The upstream portion of the second chamber 22 is delimited by a lid 31 that fits on the mouth of the cylindrical wall 29 and closes the degassing device 20. The lid 31 comprises a first wall 32, which is frusto-conical, connected to a second wall 33, which is cylindrical. Note that the first wall 32 comprises in fact two frusto-conical portions, the outer portion having an angle that is slightly larger than the angle of the inner portion. The first, frusto-conical, wall 32 is connected to the second, cylindrical, wall 33 by its smaller section. The lid 31 is secured to the cylindrical wall 29 by the larger section of its frusto-conical wall 32. The upstream portion of the second chamber 22 has therefore a decreasing cross-section. The lid 31 further comprises an inner annular shoulder 34 that extends at the junction between the frusto-conical wall 32 and the cylindrical wall 33. The opening defined by the inner annular shoulder 34 forms the opening 23 of the second chamber 22 mentioned above. The annular shoulder 34 supports the hydrophobic membrane 24 at the periphery thereof. The membrane 24 is secured to the lid 31 by an O-ring 35 resting on the shoulder 34 and against which a stopper 36 is tightly engaged. The stopper 36, which snugly fits within the cylindrical wall 33 of the lid 31, comprises a large hole 37 in its center through which the air removed from the liquid in the degassing device 30 can escape. Note that the membrane 24 does not abut on the inner surface of the stopper 36. The membrane 24 can therefore deform to a certain extent. When the positive pressure in the filter exceeds however a determined value, the membrane 24 abuts on the stopper 36 and does not run the risk of rupturing.

10

15

20

30

Three inlet ports 38, 39, 40 are connected to the first chamber 21. The inlet ports 38, 39, 40 can be used for the infusion of various liquid (e.g. a substitution liquid or a drug, when the filter is a hemofilter) and for connection to a pressure sensor.

The end-cap 5, the walls 26, 29 and 30 that delimit the first chamber 21 and the downstream portion of the second chamber 22, and the ports 25 38, 39, 40 connected thereto, can be made by molding in one piece from a plastic material. A biologically inert material like polycarbonate is appropriate when the filter is for medical use. The lid 31 can also be made in one piece by molding, from the same

material as the end-cap 5 and walls 26, 29, 30. The hydrophobic membrane 24 can be made of polytetrafluoroethylene.

5

10

15

20

25

30

The degassing device 20 is particularly adapted to remove gas from blood in an extracorporeal circuit of blood. The operation of the degassing device 20 in connection with, for example, a hemofilter, is as follows. Before a treatment session, the inlet of the first compartment (nozzle 14 of end-cap 6) of the hemofilter 1 is connected to an arterial blood line, and the outlet port 25 of the. blood degassing device 20 is connected to a venous blood line. The hemofilter 1 is engaged in a holder keeping it substantially vertical, with the degassing chamber being in the upper position. A bag of sterile saline solution is connected to the arterial line and the solution is pumped into the arterial line, the first compartment of the hemofilter 1, the degassing device 20 and the venous line, so as to rinse the extracorporeal blood circuit, to fill it with sterile saline solution and to remove air therefrom (preparatory steps called "priming" of the extracorporeal blood circuit). At the end of this process, there is no more air in the degassing device 20. Then, the arterial line is connected to a blood vessel of a patient, blood is pumped into the extracorporeal circuit while the saline solution flowing out of the venous line is collected in a waste bag. When blood reaches the end of the venous line, the venous line is in turn connected to the vessel of the patient and the treatment proper can start.

In the hemofilter 1, the blood flows within the hollow fibers 4, enters the end-cap 5, flows through the first chamber 21, pours into the second chamber 22 and leaves the degassing chamber 20 via the outlet port 25. Since the cross-section of the second chamber 22 at the level of the passageway 28 is substantially larger than the cross-section of the passageway 28 itself, the blood flow substantially decreases when blood enters the second chamber 22. This helps the bubbles and micro-bubbles that may be present in blood to move upwards by gravity towards the hydrophobic membrane 24. Also, because blood is directed by the funnel like wall 26 towards the hydrophobic membrane 24 and from then towards the frusto-conical wall 32 of the lid 31, the overall flow pattern of blood is umbrella like with a component that is tangential to the hydrophobic membrane 24. The membrane is therefore permanently swept and the creation of a layer of static blood foam on the

inner surface of the membrane 24 is prevented. Instead, in particular thanks to the frusto-conical shape of the wall 32, the bubble and micro-bubbles are kept in a permanent motion at the vicinity of the membrane 24, through which they pass shortly after entering the second chamber 22.

A prototype of the degassing device 20 was built. The diameter of the passageway 28 was 19 mm, the diameter of the second chamber 22 at the level of the passageway 28 was 32 mm, and the diameter of the membrane was 26 mm. The distance between the passageway and the hydrophobic membrane was 5mm. The membrane was made of polytetrafluoroethylene and had a thickness of 0,13 mm and a pore size of  $0.2~\mu m$ . The inner volume of the degassing device was 20 cm3. Bovine blood was circulated at a flow rate of 500ml/mn. in a closed loop circuit including a hemofilter fitted with the prototype of degassing device 20. The pressure in the degassing device was 50 mmHg. After four hours, 5 ml of air was injected in the circuit upstream of the hemofilter. After 15 minutes, the air injected in the circuit had been totally removed by the degassing device 20.

Figures 4 and 5 show a second embodiment of the invention. The main difference between this second embodiment and the embodiment of figures 1 to 3 resides in the connection of the degassing device 201 to the end cap 50. In the previous embodiment, the degassing device 20 is connected on the top of the end-cap 5 so that the central axis 27 of the degassing device 20 coincides with the central axis of the end cap 5. In the embodiments of figures 4 and 5, the degassing device 201 is laterally connected to the end-cap 50 so that the central axis 27 of the degassing device 201 is offset with respect to the central axis 3 of the end cap 50.

In more details, the end-cap 50 comprises a circular end-wall 51 connected to a tubular peripheral wall 52 by which the end-cap 50 is secured to the housing 2 of a filter. The end-cap 50 further comprises a nozzle 53 that is radially connected to the circular end wall 51 so that the longitudinal axis of the nozzle 53 is perpendicular to the central axis of the end-cap 5. The nozzle 53 is fitted with a female Luer connector.

The degassing device 201 is identical to the degassing device 20 shown in Figures 1 to 3, save for the first chamber 21, the upstream portion of which is conical, with the cross-section of the chamber 211 increasing from the inlet 54 of the chamber. Also, the degassing device 201 comprises a connecting base 55 fitted with a male Luer connector 56 complementary to the female Luer connector of the nozzle 53 of the end-cap 50. The connecting base 55 includes a channel 57 that connects the inlet 54 of the first chamber 211 to the bore of the male Luer connector 56. The longitudinal axis of the channel 57 and of the bore of male Luer connector 56 coincide and are perpendicular to the central axis 27 of the degassing device 211.

Figure 6 shows a third embodiment of an end-cap assembly according to the invention. The end-cap assembly comprises a convex, conical end-wall 60 connected to a tubular peripheral wall 61 by which the end-cap assembly can be secured to the housing of a filter. The conical end-wall 60 delimits the downstream portion of the first chamber 21 of a degassing device 202. This downstream portion has therefore a decreasing section in the direction of flow. The conical endwall 60 comprises an aperture at the tip thereof that forms a passageway 28 between the first chamber 21 and a second chamber 22. The second chamber 22 is delimited by a cylindrical wall 62 connected to the conical wall 60 so that the central axis of the cylindrical wall 62 is parallel to and offset with respect to the central axis of the conical end-wall 60, and so that the passageway 28 opens in the second chamber 22 adjacent to the cylindrical wall 62. A circular hydrophobic membrane 24 closes the mouth of the cylindrical wall 62. A capsule like lid 63 having a series of holes 64 is engaged on the cylindrical wall 62 over the hydrophobic membrane 24 so as to protect the membrane 24 from outside and to support it and limit its deformation when it is subjected to a positive pressure from inside the filter. An outlet nozzle 65 forming the outlet port 25 of the degassing device is connected to the cylindrical wall 62 opposite to the passageway 26.

30

5

10

15

20

25

The operation of the degassing device of Figure 6, when connected to an extracorporeal blood circuit, is as follows. Since the cross-section of the second chamber 22 at the level of the passageway 28 is substantially larger that the cross-section of the passageway 28 itself, the blood flow substantially decreases

when blood enters the second chamber 22. This helps the bubbles and micro-bubbles that may be present in blood to move upwards by gravity towards the hydrophobic membrane 24. Also, because blood is directed towards the hydrophobic membrane 24 at the periphery of the second chamber 22, the flow of blood has a component that is tangential to the hydrophobic membrane 24. The membrane is therefore permanently swept and the creation of a static layer of blood foam on the inner surface of the membrane 24 is prevented. Instead, the bubble and micro-bubbles are kept in a permanent motion at the vicinity of the membrane 24, through which they pass shortly after entering the second chamber 22.

Figure 7 shows a fourth embodiment of the end-cap assembly according to the invention. In this embodiment, the end-cap consists of a cylindrical peripheral wall 71 that engages the end of the housing 2 of a filter 1.

15

20

25

30

10

The cylindrical peripheral wall 71 forms the bottom part of a cylindrical wall 72 that delimits the first chamber 21 of a degassing chamber 203. The first chamber 21 has a constant circular cross-section and its diameter is the same as the internal diameter of the end of the housing 2. The first chamber 21 opens into a second chamber 22 delimited by a cylindrical wall 73, which is concentric to the cylindrical wall 72 of the first chamber 21, and a bottom wall 74 that is beveled with respect to the longitudinal axis 27 of the concentric cylindrical walls 72, 73. The passageway 28 between the two chambers 21, 22 has the same cross-section as the end of the housing 2 of the filter 1 and a flow of liquid circulated in the first chamber of the filter 1 passes therefore unimpeded from the hollow fibers 4 into the second chamber 22. The cross-section of the second chamber 22 at the level of the passageway 28 is larger than the cross-section of the passageway 28 and the second chamber 22 therefore forms an overflow for the first chamber 21. The upper part of the wall 73 that delimit the second chamber 22 is curved towards the central axis 27 of the degassing device 203 so as to form an annular shoulder 74 surrounding an opening 23 of the second chamber 22. A hydrophobic membrane 24 is secured at its periphery to the annular shoulder 74. A capsule like lid 75 having a series of holes 76 is engaged in the opening 23 of the second chamber 22 so as to protect the membrane 24 from outside and to support it and limit its

deformation when it is subjected to a positive pressure from inside the filter. The degassing device 203 comprises an outlet port 25 connected to the second chamber 22.

The operation of the degassing chamber 203 is not substantially different from the 5 operation of the embodiment of the figures 1 to 4.

Claims

5

10

20

1. End-cap assembly for a filtration device (1) comprising a filtration membrane (4) arranged in an elongated housing (2) so as to delimit therein a first and a second compartments,

the end-cap assembly comprising:

- an end-cap (5, 50) having a peripheral wall (16, 52, 61, 71) for connection to an end of the housing (2); and
- a degassing device (20, 201, 202, 203) connected to the end-cap (5, 50), comprising:
- a first chamber (21) for receiving a liquid flowing out of the first compartment into the end-cap (5, 50),
- a second chamber (22) in communication with the first chamber (21) and having an opening (23) closed by a hydrophobic membrane (24), and
- an outlet port (25) connected to the second chamber (22) for discharging the liquid.
  - 2. End-cap assembly according to claim 1, wherein the second chamber (22) is in communication with the first chamber (21) through a passageway (28) that has a lesser cross-section than a cross-section of the second chamber (22) so that a flow of liquid from the first chamber (21) into the second chamber (22) decreases within the second chamber (22).
- 3. End-cap assembly according to claim 2, wherein the first chamber (21), the second chamber (22) and the passageway (28) therebetween are arranged with respect to each other so that a flow pattern of a liquid flowing from the first chamber (21), through the second chamber (22) and to the outlet port (25) comprises a component that is tangential to the membrane.
- 4. End-cap assembly according to claim 3, wherein the flow pattern of a liquid flowing from the first chamber (21), through the second chamber (22) and to the outlet port (25) comprises an umbrella like component.

- 5. End-cap assembly according to claim 2, wherein the first chamber (21), the second chamber (22) and the passageway (28) therebetween are arranged with respect to each other so that a flow of liquid flowing from the first chamber (21), through the second chamber (22) and to the outlet port (25) keeps gas bubbles in motion along an inner surface of the hydrophobic membrane (24).
- 6. End-cap assembly according to claim 2, wherein the housing, the first chamber (21) and the passageway (28) have substantially the same cross-section.
- 7. End-cap assembly according to claim 2, wherein the first chamber (21) comprises a downstream portion having a cross-section that is substantially the same as the cross-section of the passageway (28) between the first and the second chamber (22).
- 8. End-cap assembly according to claim 7, wherein the first chamber (21) comprises an upstream portion having a decreasing cross-section, with a larger cross-section that is substantially the same as the cross-section of the housing and a smaller cross-section that is substantially the same as the cross-section of the passageway (28) between the first chamber (21) and the second chamber (22).
  - 9. End-cap assembly according to one of the claims 2 to 8, wherein the second chamber (22) has a downstream portion that surrounds the passageway (28) and forms an overflow for a fluid flowing from the first chamber (21) into the second chamber (22).
  - 10. End-cap assembly according to claim 9, wherein the cross-section of the passageway (28) is substantially circular and the cross section of the second chamber (22) that is level with the passageway (28) is substantially annular.

11. End-cap assembly according to claim 10, wherein the ratio of the diameter of the passageway (28) to the diameter of the second chamber (22) at the level of

the passageway (28) is comprised between about 0.2 and about 0.5.

30

25

5

12. End-cap assembly according to claim 11, wherein the ratio of the diameter of the passageway (28) to the diameter of the second chamber (22) at the level of the passageway (28) is about 0.35.

13. End-cap assembly according to one of the claims 9 to 12, wherein the upstream portion of the second chamber (22) has a decreasing cross-section, with a larger cross-section that is substantially level with the passageway (28) and a smaller cross-section that is substantially level with the hydrophobic membrane (24).

10

20

25

- 14. End-cap assembly according to claim 13, wherein the upstream portion of the second chamber (22) is substantially frusto-conical.
- 15. End-cap assembly according to one of the claims 9 to 13, wherein the second chamber (22) has a downstream portion that extends at least in part around the downstream portion of the first chamber (21).
  - 16. End-cap assembly according to of the claim 15, wherein the outlet port (25) opens into the downstream portion of the second chamber (22) at a location remote from the passageway (28).
  - 17. End-cap assembly according to claim 2, wherein the first chamber (21) comprises a downstream portion that is substantially conical and the passageway (28) between the first and the second chamber (22) opens in the first chamber (21) at the tip of the cone.
  - 18. End-cap assembly according to claim 17, wherein the second chamber (22) Thas a periphery and the passageway (28) between the first and the second chamber (22) at the periphery thereof.

30

19. End-cap assembly according to one of the claims 17 and 18, wherein the outlet port (25) opens into the second chamber (22) in a location remote from the passageway (28).

- 20. End-cap assembly according to any of the claims 1 to 19, further comprising an inlet port (38, 39, 40) for the infusion of liquid.
- 21. End-cap assembly according to any of the claims 1 to 20, further comprising a pressure measurement port (38, 39, 40) for connection to a pressure sensor.
  - 22. End-cap assembly according to any of the claims 1 to 21, further comprising a support member (36, 63, 75) secured to the second chamber (22) close to the hydrophobic membrane (24) so as to limit the deformation of the hydrophobic membrane (24).

10

15

- 23. End-cap assembly according to any of the claims 1 to 22 for closing a housing (2) of a filter device (1) having a longitudinal axis (3), wherein the hydrophobic membrane (24) is arranged in a plane substantially perpendicular the longitudinal axis (3).
  - 24. Filtration device (1) comprising an end-cap according to one of the claims 1 to ... 23.
- 25. Filtration device (1) according to claim 24, wherein the filtration membrane comprises a bundle of hollow fibers (24) that is secured at both ends within the housing by two discs (7) of potting material having an outer surface (8) on which the ends of the hollow fibers (4) open, and wherein the first chamber (21) comprises the channels inside the fibers and a space delimited within the end-caps (5, 50) and the second chamber (22) comprises a space around the fibers that is delimited by the housing (2) and an inner surface (9) of the two discs (7) of potting material.
- 26. Filtration device (1) according to one of the claims 24 and 25, for the extracorporeal treatment of blood.
  - 27. Blood degassing device (20, 201, 202, 203) comprising:
  - a first chamber (21) having an inlet for receiving a flow of blood to be degassed;

- a second chamber (22) in communication with the first chamber (21) and having an opening closed by a hydrophobic membrane (24); and
- an outlet port (25) connected to the second chamber (22) for discharging blood, wherein the second chamber (22) is in communication with the first chamber (21) through a passageway (28) that has a lesser cross-section than a cross-section of the second chamber (22) so that a flow of blood from the first chamber (21) into the second chamber (22) decreases within the second chamber (22).
- 28. Blood degassing device (20, 201, 202, 203) according to claim 27, wherein the first chamber (21), the second chamber (22) and the passageway (28) therebetween are arranged with respect to each other so that a flow pattern of blood flowing from the first chamber (21), through the second chamber (22) and to the outlet port (25) comprises a component that is tangential to the membrane.

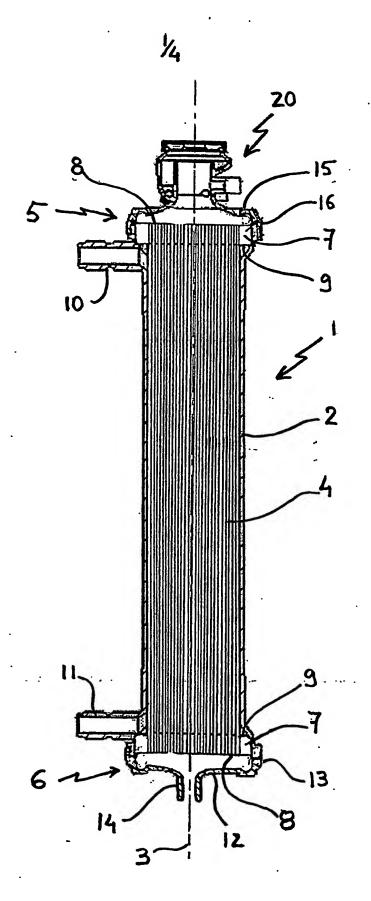
10

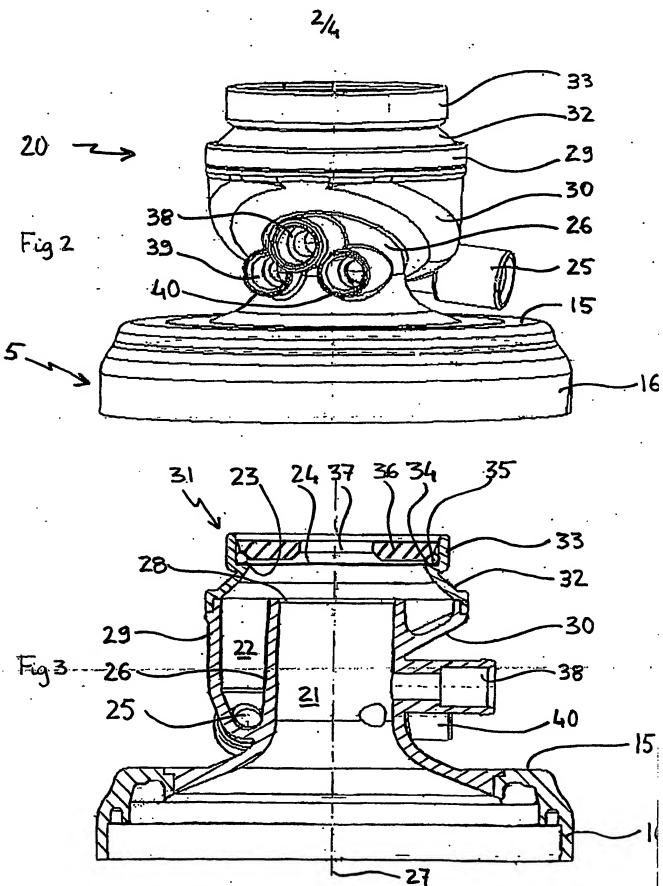
- 29. Blood degassing device (20, 201, 202, 203) according to one of the claims 27 and 28, wherein the flow pattern of blood flowing from the first chamber (21), through the second chamber (22) and to the outlet port (25) comprises an umbrella like component.
- 30. Blood degassing device (20, 201, 202, 203) according to one of the claims 27 and 29, wherein the first chamber (21), the second chamber (22) and the passageway (28) therebetween are arranged with respect to each other so that a flow of blood flowing from the first chamber (21), through the second chamber (22) and to the outlet port (25) keeps gas bubbles in motion along an inner surface of the hydrophobic membrane (24).

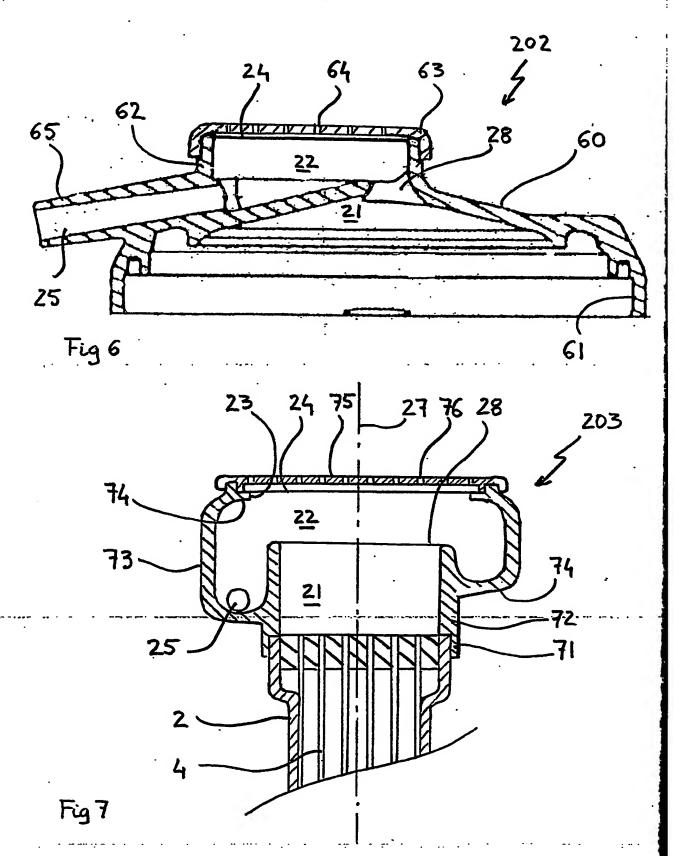
### **Abstract**

An end-cap assembly is part of a filtration device (1) that comprises a filtration membrane (4) arranged in an elongated housing (2) so as to delimit therein a first and a second compartments. The end-cap assembly includes:

- an end-cap (5) having a peripheral wall (16) for connection to an end of the housing (2); and
- a degassing device (20) connected to the end-cap (5), comprising:
- a first chamber (21) for receiving a liquid flowing out of the first compartment into the end-cap (5),
- a second chamber (22) in communication with the first chamber (21) and having an opening (23) closed by a hydrophobic membrane (24), and
- an outlet port (25) connected to the second chamber (22) for discharging the liquid.







# This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:
BLACK BORDERS
☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
FADED TEXT OR DRAWING
BLURRED OR ILLEGIBLE TEXT OR DRAWING
☐ SKEWED/SLANTED IMAGES
☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
☐ GRAY SCALE DOCUMENTS
LINES OR MARKS ON ORIGINAL DOCUMENT
☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
□ other:

# IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.